**Application No.: 10/705,195** 

#### REMARKS

Claims 1-16 are pending and claims 6-9, 15 and 16 are withdrawn from consideration.

Claim 1 has been amended by deleting the hybridization language and introducing the term "isolated" in the preamble and percent identity language. Support for the amendment can be found in the Specification on page 8, lines 13-15.

New claim 17 has been added. Support for this claim can be found in the Specification on page 8, lines 13-15.

No new matter has been added.

## Rejections Under 35 USC § 101

The Examiner has rejected claim 1 as drawn to non-statutory subject matter for failure to state that the nucleic acid is isolated.

Applicants have amended the claim to recite "isolated," thereby overcoming the rejection.

### Rejections Under 35 USC § 112, First Paragraph

#### Enablement

The Examiner has rejected claims 1-5 and 10-14 as not enabled, commenting that the term "hybridizes" is interpreted to read on any length of sequence capable of hybridizing under any conditions to the claimed sequences. In addition the Examiner contends that the function of a starch branching enzyme (SBE) is unpredictable, alleging that Tetlow et al. discloses that "only a few genetic variations that lead to known phenotypes are ever known for SBEs." Applicants respectfully traverse.

First, Applicants have deleted the hybridization language from the claims, replacing it with percent identity language, thereby overcoming this aspect of the rejection.

Second, it appears that the Examiner forms his opinion of Tetlow's teaching based on the following citation: "To date, only mutations in SBEII isoforms give clear phenotypes, and in monocots this is confined to SBEIIb mutants" (page 2134, right-hand column, last paragraph). But the Examiner has interpreted Tetlow's teachings wrongly and the conclusion that "only a few genetic variations that lead to known phenotypes are ever known for SBEs" <u>cannot</u> be drawn from the Tetlow paper. Rather, <u>Tetlow teaches</u> that in some cases a starch structure remains unaltered in spite of down-regulation or elimination of branching enzyme genes in plants.

It seems that the Examiner interprets Tetlow's use of the word "mutation" to mean a mutation in the amino acid sequence of a branching enzyme or in the corresponding nucleotide sequence. But this is not the case. It is important to understand that when Tetlow speaks about a "mutation" he is referring to down-regulation or elimination (knock out) of SBE genes. See, for example, the literature cited by Tetlow: Satoh (2003b) entitled "Starch branching enzyme I-deficient mutation" and Filpse, entitled "Introduction of sense and antisense cDNA..." Moreover, on page 2134 Tetlow deals with down-regulation or knock out of plant SBE genes and not with the overexpression of a branching enzyme from a Neisseria species, as taught by the present invention.

On page 2134, cited by the Examiner, Tetlow deals with starch modification by manipulation of SBEs in plants and examines the role of the plant SBEI and SBEII in starch synthesis. Tetlow teaches that "only mutations in SBEII isoforms give clear phenotypes [i.e. starch phenotypes] and in monocots this is confined to SBEIIb mutants." On the other hand, mutations of SBEI are described to have minimal effects on starch synthesis and structure (see "Tetlow, page 2134, right-hand column, last paragraph: "*Down-regulation or elimination* of SBEI activity... appears to have minimal effects on

starch synthesis..." (emphasis added). With respect to SBEIIa, Tetlow discloses that a mutation of that enzyme does not alter the storage starch of the endosperm.

Thus, as is evident from the above, when speaking of a "mutation," Tetlow clearly means down-regulation or elimination of a gene. In view of this, a person skilled in the art would at best derive from the cited passages in Tetlow that down-regulation or elimination of an SBEIIb gene, but not of an SBEI gene, can be expected to alter the starch phenotype in plants. Furthermore, a skilled person would derive from Tetlow that down-regulation or elimination of the SBEIIa gene would probably not have effects on the endosperm starch structure. But certainly Tetlow does **not** teach that a branching enzyme activity is lost by variation in the amino acid sequence of any SBE.

In view of the above, Applicants respectfully request reconsideration and removal of the rejection.

## Written Description

The Examiner has rejected claims 1-5 and 10-14 as lacking written description, commenting that the term "hybridizes" is interpreted to read on any length of sequence capable of hybridizing under any conditions to said sequences. Applicants respectfully traverse.

First, Applicants have deleted the hybridization language from the claims, replacing it with percent identity language, thereby overcoming the rejection.

Second, the identity language provides that the claimed nucleic acid is not merely defined by functional characteristics, but by structural characteristics. Furthermore, it is possible to visualize and recognize the claimed species and to clearly distinguish the claimed nucleic acids from other materials.

In view of the above, Applicants respectfully request reconsideration and removal of the rejection.

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# Rejections Under 35 USC § 112, Second Paragraph

The Examiner has rejected claims 1-5 and 10-14 as indefinite for recitation of "nucleic acid molecules" in parts a-g of claim 1.

Applicants have amended the claims by replacing "nucleic acid molecules" with the phrase "nucleic acid molecule," thereby overcoming the rejection.

## Conclusion

Applicants submit that all of the claims pending in the application represent novel, unobvious and patentable subject matter. Accordingly, Applicants request removal of all rejections and allowance of the claims.

Should the Examiner have any questions or concerns, he is encouraged to telephone Susan W. Gorman (Reg. No: 47,604) to discuss the case and to set up an Interview.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit overpayment to Deposit Account No: 02-2448 for any additional fees required under 37 C.F.R § 1.16 or under 37 C.F.R § 1.17; particularly extension of time fees.

Dated: January 19, 2007

Respectfully submitted,

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